

Ointment of wool alcohols, preserved

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 13/08/2012 Revision date: 21/04/2017

1920820

Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixtures
Product name : Ointment of wool alcohols, preserved
Product code : 1920820
Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - The Netherlands
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Purified water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	49.5	Not classified
Paraffin, white soft		46.75	Not classified
Wool alcohols	(CAS-No.) 8027-33-6 (EC-No.) 232-430-1	3	Not classified
Cetostearyl alcohol	(CAS-No.) 67762-27-0 (EC-No.) 267-008-6 (REACH-no) 01-2119485905-24-0007, 01-2119485905-24-0006, 01-2119485907-20-0006, 01-2119485907-20-0005	0.25	Not classified
Methyl parahydroxybenzoate	(CAS-No.) 99-76-3 (EC-No.) 202-785-7	0.0375	Not classified
Propyl parahydroxybenzoate	(CAS-No.) 94-13-3 (EC-No.) 202-307-7	0.0125	Not classified

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Not applicable.
First-aid measures after skin contact : Wash skin with mild soap and water.
First-aid measures after eye contact : Rinse with water. If eye irritation persists, take medical advice.
First-aid measures after ingestion : Drink plenty of water. Induce vomiting. Seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

Fire hazard : This product is flammable. On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide.

Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

Precautionary measures fire : Exercise caution when fighting any chemical fire.

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up, shovel or vacuum.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store in dry, well-ventilated area.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Hand protection:

No specific measures are necessary

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Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Not required

Respiratory protection:

None necessary

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Paste.
Colour	: White.
Odour	: weak.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 0.96 g/cm ³ 20°C
Solubility	: Material nearly insoluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

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10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

heat. High temperature. Moisture.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Paraffin, white soft	
LD50 oral rat	> 5000 mg/kg
Cetostearyl alcohol (67762-27-0)	
LD50 oral rat	> 5000 mg/kg
Wool alcohols (8027-33-6)	
LD50 oral rat	> 42700 mg/kg Dissolved in oil.
Methyl parahydroxybenzoate (99-76-3)	
LD50 oral rat	2280 mg/kg
Propyl parahydroxybenzoate (94-13-3)	
LD50 oral rat	> 5000 mg/kg

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Cetostearyl alcohol (67762-27-0)	
LC50 fish 1	> 100 mg/l

12.2. Persistence and degradability

Paraffin, white soft	
Biodegradation	96 % 16 d

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Cetostearyl alcohol (67762-27-0)	
Persistence and degradability	readily degradable in water.
BOD (% of ThOD)	> 60 % ThOD

Wool alcohols (8027-33-6)	
Persistence and degradability	Biodegradable.

Propyl parahydroxybenzoate (94-13-3)	
Persistence and degradability	readily degradable in water.
Biodegradation	> 95 %

12.3. Bioaccumulative potential

Cetostearyl alcohol (67762-27-0)	
Log Pow	6.7 - 7.4

Propyl parahydroxybenzoate (94-13-3)	
Log Pow	3.04

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

No data available

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- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
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Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

Data sources : Supplier.

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product